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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,522	09/28/2001	Thomas Krah	Bayer 10,139.3-KGB	5606

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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/966,522

Applicant(s)

KRAHN ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-42 is/are pending in the application.
- 4a) Of the above claim(s) 6-16 and 24-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 6-42 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 09/194,099.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 . 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 6-16, 36, 38-42, drawn to a method for reducing non-specific background light, classified in class 436, subclass 546.
- II. Claims 17-23, drawn to a kit comprising of fluorescent dye and a masking dye, classified in class 252, subclass 408.1.
- III. Claims 24-31, 37 drawn to a composition of matter comprising a biological cell, an aqueous solution with a masking dye, classified in class 435, subclass 325.
- IV. Claims 32-35, drawn to a method of identifying a chemical with a detection step, classified in class 436, subclass 518.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together because invention I is a method of reducing non-specific background without a detection step while the method of group IV is a method of identifying a chemical, which has a detection, step. The two methods have different modes of operation, different functions and different effects.

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Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together because the method of reducing non-specific background does not require a fluorescent dye. The two inventions have different functions and different effects. The same applies for inventions I and III; and inventions II & IV.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together because they have different functions and would provide different effects. Invention II is a kit comprising of a fluorescent dye and a masking dye while invention III is a composition comprising a biological cell and a masking dye.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II, III or IV, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Kurt Biscoe on December 15, 2003 a provisional election was made with traverse to prosecute the invention of Group II, claims 17-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-16, 24-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Following is an action for claims 17-23:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17, last line, is indefinite for reciting "said photon reducing agent". "Said photon reducing agent" lacks antecedent support.

Claim 22 is indefinite because it recites a trademark "Brilliant Black". Please substitute the generic compound name for the trademark.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17- 20, 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Cubbage et al. (US 5,582,982).

Cubbage et al. teach a kit comprising a fluorescent probe and a background-reducing compound. The background-reducing compound comprises a light-absorbing moiety with a structure different than that of the fluorescent dye moiety of the fluorescent probe and having an absorption wavelength range that includes of the emission wavelengths of the fluorescent probe at which the amount of light is measured. If the amount of light emitted exceeds a certain specified amount, the cell is considered to have target molecules. The background-reducing compound will absorb emissions from the fluorescent probe. In addition, the background-reducing compound will absorb light emitted due to autofluorescence by non-probe molecules present in the biological entity. Background-reducing compounds may be staining dyes, such as azo

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dye derivatives. (See also col. 2, line 45-col. 7, line 27). Regarding the functional limitations such as the masking dye is present in solution at an amount sufficient to reduce non-specific background light emitted from said solution by at least 15%, 30%, 50% or 70% compared to the non-specific background light emitted from said solution in the absence of said masking dye, if the masking dye in Cubbage has an absorption spectrum that overlaps with the emission and/or excitation spectrum of said fluorescent dye, then the masking dye would inherently reduce non-specific background by at least 15%, 30%, 50% or 70%. Thus, the masking dye in Cubbage would inherently improves the optical signal-to-noise ratio by at least 300%. Regarding the limitation that the fluorescent dye detects a voltage across the membrane of the biological cell, it is inherent that Cubbage teaches these limitations because if the fluorescent dye is present, then it would comprise all the functional limitation such as detecting the voltage across the membrane of the biological cell.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cubbage et al. (US 5,582,982) in view of Van Aken (US 5,489,537).

Cubbage has been discussed above.

However, Cubbage fails to teach Brilliant Black as a masking dye.

Van Aken teaches a method and kit for determining the presence or absence of a substance by detection of a colloidal dye associated with agglutinated particles. The colloidal dye is a background-enhancing dye which reduces non-specific background to enhance optical detection. The background-enhancing dye is a water-soluble dye such as Brilliant Black. (see col. 21, lines 58-67).

It would have been obvious to one of ordinary skills in the art to use Brilliant Black as a background-enhancing dye in the kit for use in the method of Cubbage because both references teach using dye as a background reducing agent in assay. Since Brilliant Black is known for enhancing the background in an assay which use optical detection, it would motivate one of ordinary skills in the art to use Brilliant Black in assays such as one taught by Cubbage because Cubbage teaches using fluorescent label which is known for producing non-specific background.

#### ***Allowable Subject Matter***

Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art fails to teach that the fluorescent dye is permeable to the membrane of the biological cells.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do  
Patent Examiner  
December 22, 2003



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641